

## REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1-18 are pending. The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. For example, independent claim 1 is based on the original claims, page 2 lines 5-14 of the specification, and the example on page 5-6 of the specification; independent claim 9 is based on the original claims with the food being shredded cheese (original claim 12), the polyene antifungal compound being natamycin (page 3 line 20 of the specification), and the aqueous composition being sprayed onto shredded cheese with the thickening agent used to prevent clogging of the spray nozzles (page 3 lines 15-17 of the specification).

Support for claims 2-3 and 10-11 can be found, inter alia, at page 3 lines 28-30 of the specification. Support for claims 4 and 12 can be found, inter alia, at page 3 line 26 of the specification; support for claims 5 and 13 can be found, inter alia, at page 4 line 2 of the specification. Support for claims 6 and 16 can be found, inter alia, at page 4 lines 27-31 of the specification. Support for claims 7 and 17 can be found, inter alia, at page 4 line 16; support for claims 8 and 18 can be found, inter alia, at page 4 line 24 of the specification. Support for claim 14 may be found, inter alia, at page 4 lines 7-8 of the specification. Support for claim 15 may be found, inter alia, at page 4 lines 13-14 of the specification.

A supplemental Information Disclosure Statement is being submitted herewith; the required Official fee in lieu of certification is also submitted herewith.

### *35 U.S.C. 103 – Nonobviousness*

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03. A claimed invention is unpatentable if the differences between it and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Kahn*, 78 USPQ2d 1329, 1334 (Fed. Cir. 2006) citing the legal standard provided in *Graham v. John Deere*, 148 USPQ 459 (1966). The *Graham* analysis needs to be made explicitly. *KSR v. Teleflex*, 82 USPQ2d

1385, 1396 (2007). It requires findings of fact and a rational basis for combining the prior art disclosures to produce the claimed invention. See *id.* (“Often, it will be necessary for a court to look to interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue”). The use of hindsight reasoning is impermissible. See *id.* at 1397 (“A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning”). Thus, a *prima facie* case of obviousness under Section 103(a) requires “some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct.” *Kahn*, 78 USPQ2d at 1335; see *KSR*, 82 USPQ2d at 1396. A claim which is directed to a combination of prior art elements “is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 1396. Finally, a determination of *prima facie* obviousness requires a reasonable expectation of success. See *In re Rinehart*, 189 USPQ 143, 148 (C.C.P.A. 1976).

Claims 1-23 were rejected under Section 103(a) as allegedly unpatentable over Isom et al. (EP 1,174,039) and Ang (EP 1,068,809) in view of Noordam et al. (US 5,552,151), De Haan et al. (EP 867,124), and Schuppiser et al. (US 5,446,014). Applicants traverse because independent claims 1 and 9 are directed to solving the problem of clogging of spray nozzles when treating shredded cheese with an aqueous composition containing natamycin by including a thickening agent in the aqueous composition to prevent clogging of the nozzles during spraying.

Applicants submits herewith the master’s thesis of Eric C. Suloff entitled *Comparative Study of Semisynthetic Derivative of Natamycin and the Parent Antibiotic on the Spoilage of Shredded Cheddar Cheese* which is helpful in assessing nonobviousness of their claimed invention. It is the closest prior art known to Applicants because Suloff discloses a method for preventing nozzle clogging during spraying of shredded cheese with an aqueous composition comprising natamycin to protect against fungal spoilage (see page 24 lines 6-8 of Suloff). But note that the thesis neither teaches nor suggests

including a thickening agent in the aqueous composition to prevent nozzle clogging. This solution with its unexpected results is taught by Applicants in their specification.

According to Applicants' invention, the presence of a thickening agent in the aqueous composition containing natamycin prevents nozzle clogging, which otherwise occurs when spraying shredded cheese with the aqueous composition. There is no evidence of record that there was a teaching or suggestion that the presence of a thickening agent in the aqueous composition containing natamycin would have this effect. Instead, Suloff discloses that this problem is solved by using chemical derivatives of natamycin which do not cause nozzle clogging. The disadvantage of this solution is that the antifungal activity of Suloff's chemical derivatives of natamycin is much less than of the unmodified natamycin (see pages 59-68, especially page 68 lines 9-14, of Suloff). Therefore, Suloff teaches away from Applicants' invention.

The Isom et al. document (EP 1 174 039) relates to the problem of preparing shredded cheese with excellent organoleptic and nonagglomeration properties, while improving nutritional fortification of the shredded cheese (see column 2 lines 12-15). Isom et al. solve this problem by adding a nutritional supplement comprising calcium sulphate dehydrate to the shredded cheese. By adding this supplement, the levels of anticaking agents commonly present in considerable amounts in shredded cheese can be reduced (see column 2 lines 36-41). Isom et al. further disclose that natamycin can be added to the shredded cheese. The use of a thickening agent, however, to prevent nozzle clogging during spraying of an aqueous composition containing natamycin on shredded cheese is neither taught nor suggested. Therefore, Applicants' claims 1 and 9 are not rendered obvious over Isom et al. in combination with any of the other prior art documents of record.

The Ang document (EP 1 068 809) relates to the problem of how to increase the bioavailability of natamycin (see page 2: paragraph [0008]). Ang solves this problem by reducing the average particle size of natamycin to below 10 microns (see page 3: paragraphs [0017] and [0018]). It further discloses that the natamycin can be added to the shredded cheese by dry mixing instead of spraying. Use of thickening agent to prevent nozzle clogging during spraying of an aqueous composition containing natamycin on

shredded cheese is neither taught nor suggested. Ang teaches away from Applicants' solution to the problem of nozzle clogging. Therefore, Applicants' claims 1 and 9 are not rendered obvious over Ang in combination with any of the other prior art documents of record.

The Schuppiser et al. document (US 5,446,014) relates to the problem of nozzle clogging of aqueous formulations of quaternary ammonium hydroxides and xanthan gum due to the formation of insoluble fibers (see column 1 lines 53-61). Separating the mixing of an anticaking agent with shredded cheese from the spraying of shredded cheese with an aqueous composition containing natamycin is not addressed, nor does it appear to have been contemplated. Schuppiser et al. provide a solution to the problem of clogging by using an amount of xanthan gum having an intrinsic viscosity of less than  $3,500 \text{ cm}^3/\text{g}$  (see column 2 lines 24-31). Applicants submit that one of ordinary skill in the art would not have looked to Schuppiser et al. to solve the instant problem of nozzle clogging when spraying shredded cheese with an aqueous composition containing natamycin. It is submitted that one of ordinary skill in the art seeking a solution to a given problem in a specific technical field (e.g., preparation of shredded cheese) would look at analogous arts. Schuppiser et al. is not in the same or similar technical field because the document relates to spraying a pesticide on agricultural crops. Useful solutions for the problem of nozzle clogging when spraying natamycin compositions might be solved, however, would be found in documents within the relevant field of food preparation instead of agriculture. In view of the fact that the above-cited documents do provide alternative solutions to the problem of nozzle clogging by an aqueous composition containing natamycin, Applicants submit that one of ordinary skill in the art would not have strayed into the unrelated field of spraying pesticides on agricultural crops as evidenced by Schuppiser et al.

Moreover, the field of Schuppiser et al. is given by its international patent classification (IPC) number A01N (Preservation of Plants) while the instant invention has the different IPC number A23C (Dairy Products). The classification of Schuppiser et al. is additional evidence that it is nonanalogous art because one of ordinary skill in the art

would not have referred to the specific technical field of Preservation of Plants to solve the problem of nozzle clogging during the preparation of dairy products.

Even if one of ordinary skill in the art would have considered Schuppiser et al. to solve the problem of nozzle clogging of aqueous compositions containing natamycin, which is however disputed, he would not have contemplated using a thickening agent to solve the problem of nozzle clogging during spraying. Schuppiser et al. use quaternary ammonium compounds which are active as pesticides for agricultural crops. Quaternary ammonium compounds are structurally different from a polyene antifungal compound like natamycin; they also have different chemical properties. There is no evidence of record that an aqueous composition containing natamycin could be used in the methods of Schuppiser et al. with a reasonable expectation of success. One of ordinary skill in the art would have no reason to replace quaternary ammonium compounds with natamycin. On the contrary, such a person would have had serious doubts as to whether Schuppiser et al. and their methods would be applicable to an aqueous composition containing natamycin. It is submitted that any argumentation to the contrary is based on hindsight. In view of the above, Applicants' claims 1 and 9 are not rendered obvious over Schuppiser et al. in combination with any of the other prior art documents of record.

The Noordam et al. document (US 5, 552,151) is directed to a different problem: providing concentrated suspensions of natamycin having good chemical, microbial, and physical stability (see abstract). Noordam et al. solve this problem by preparing concentrated stock suspensions containing a specific amount of natamycin and a thickening agent in an amount that the viscosity of the concentrated suspensions is 500 mPa or more within a specific pH range (see column 8 lines 21-26). As Noordam et al. are concerned with the problem of providing chemically, microbially, and physically stable concentrated aqueous stock suspensions of natamycin instead of the problem of nozzle clogging by an aqueous composition containing natamycin, the cited document neither teaches nor suggests that inclusion of a thickening agent can be used to prevent nozzle clogging when spraying the aqueous composition containing natamycin. Therefore,

Applicants' claims 1 and 9 are not rendered obvious over Noordam et al. in combination with any of the other prior art documents of record.

Finally, the de Haan et al. document (EP 0 867 124) is directed to an aqueous composition containing natamycin and xanthan gum. But an anticaking agent is not mixed with the shredded cheese before spraying with the aqueous composition. Neither is the problem of clogging of nozzles during such spraying addressed. De Haan et al. describe the problem of how to increase the efficacy of natamycin as an antifungal agent (see page 2 lines 18-22) by including a thickening agent in the aqueous composition (see page 2 line 57 to page 3 line 2). In view thereof, one of ordinary skill in the art would not have separated mixing with anticaking agent and from spraying with aqueous composition, nor would thickening agent have been used to prevent nozzle clogging. Therefore, Applicants' claims 1 and 9 are not rendered obvious over de Haan et al. in combination with any of the other prior art documents of record.

The Examiner's attention is also directed to Koontz & Marcy (J. Agric. Food Chem. 51:7106-7110, 2003) which is submitted herewith. It was published after this application's priority date and is submitted solely to show that one of ordinary skill in the art seeking a solution for the problem of nozzle clogging by an aqueous composition containing natamycin at the time this application was filed found a solution completely different from Applicants' solution of their claimed invention. Koontz & Marcy describe on page 7106, left column, lines 13-17 that clogging of spray nozzles is a problem associated with aqueous compositions containing natamycin. But the solution to this problem disclosed in Koontz & Marcy is to form cyclodextrin inclusion complexes with natamycin. Formation thereof leads to an increase in the solubility of natamycin and consequently prevents clogging of spray nozzles during preparation of shredded cheese (see page 7110, left column, lines 3-10). This teaches away from Applicants' solution.

For the reason discussed above, the cited prior art documents does not render obvious Applicants' claimed invention because all limitations of independent claim 1 or 9 are not fairly taught or suggested therein. Moreover, claims depending from the independent claims are also not made obvious by the documents because the limitations of

claim 1 or 9 are incorporated in the dependent claims. M.P.E.P. § 2143.03 citing *In re Fine*, 5 USPQ2d 1596 (Fed. Cir. 1988).

Withdrawal of the Section 103 rejection is requested because the claimed invention would not have been obvious to the ordinarily skilled artisan at the time Applicants made their invention.

*Conclusion*

Having fully responded to the pending Office Action, Applicants submit that the claims are in condition for allowance and earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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